

REMARKS

Applicant respectfully requests entry of the amendments and remarks submitted herein. Claims 1, 5, and 11 have been amended and claim 6 has been canceled without prejudice to continued prosecution. Claims 1-5, 7-14, 24, and 25 are currently pending. Reconsideration of the pending application is respectfully requested.

Objections to the Specification

The disclosure stands objected to because the disclosure fails to provide the headings indicated by the Examiner. Applicants thank the Examiner for suggestions regarding the arrangement of the specification, but do not wish to amend the present specification at this time. Applicants respectfully request that the application be examined as filed.

The disclosure also stands objected to because of the paragraph on page 3, lines 29-31. The specification was amended to remove that particular paragraph in the Preliminary Amendment of February 14, 2002. Therefore, Applicants respectfully submit that the objection to the specification is moot.

The 35 U.S.C. §112 Rejections

Claims 1-5 and 7-10 stand rejected under 35 U.S.C. §112, first paragraph, as the Examiner asserted that the specification, while being enabling for plasma, blood, saliva, and urine samples, does not reasonably provide enablement for any and all body fluid samples.

Without acquiescing to the Examiner's rejection, Applicant has amended claim 1 herein to incorporate the language of claim 6. As claim 6 is not rejected for lack of enablement, Applicant respectfully requests that the rejection of claims 1-5 and 7-10 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claims 1-14, 24, and 25 stand rejected under 35 U.S.C. §112, second paragraph, as the Examiner asserted that those claims are indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. This rejection, in part, is respectfully traversed.

The Examiner asserted that claim 1 is indefinite for the recitation of "blood clotting status." Without acquiescing to the Examiner's rejection, Applicant has amended claim 1 herein to recite that the blood clotting status is the blood clotting status INR, which refers to the International Normalized Ratio. In view of this amendment, the use of "blood clotting status INR" in claim 1 is not indefinite.

The Examiner asserted that claim 4 is indefinite because it is unclear what Applicant intends, and because the use of the term "a combined signal correlating therewith" is vague and indefinite. First, it is intended that the step recited in claim 4 replace step b) of claim 2. Claim 4 would be understood by those of skill in the art to be a combined signal which is, for example, produced by individual signals acting together. The combined signal may be, for example, a combined or a mixed color generated by individual fluorescent signals or the like. Applicant respectfully refers the Examiner to page 6, lines 5 to 37 of the specification, where the intended meaning of claim 4 is clearly described.

The Examiner asserted that the use of "in particular" in claim 5 is vague and indefinite. Without acquiescing to the Examiner's rejection, Applicant has herein amended claim 5 to remove such language.

The Examiner asserted that the phrase "or the like" in claim 6 is vague and indefinite. Applicant notes that claim 6 has been canceled without prejudice to continued prosecution, and the language of claim 6 has been incorporated into claim 1.

The Examiner asserted that the use of "generate a combined signal" in claim 11 is vague and indefinite. Although Applicant respectfully disagrees with the Examiner, in order to expedite prosecution, Applicant has amended claim 11 to recite that "the labeling substances are selected so that they are able together to generate a combined signal, wherein said combined signal represents C1 + C2." Support for this amendment can be found, for example, throughout the specification. See, for example, page 6, lines 5-37, page 7, lines 17-21, and page 9, lines 8-16.

In view of the amendments and remarks herein, Applicant respectfully requests that the rejection of claims 1-14, 24, and 25 under 35 U.S.C. §112, second paragraph, be withdrawn.

The 35 U.S.C. §102 Rejections

Claims 11, 12, and 14 stand rejected under 35 U.S.C. §102(b) as being anticipated by Furie et al. (U.S. Patent No. 4,769,320). The Examiner asserted that Furie et al. disclose the same components as the instant claims. The Examiner also asserted that the intended use recited in claim 11 (i.e., "for carrying out the method as claimed in claim 1") must result in a structural difference between the claimed invention and the prior art to patentably distinguish the claimed invention from the prior art. This rejection is respectfully traversed.

The antibodies described by Furie et al. are "incorporated into two separate immunoassays" (column 6, lines 13 and 14). In contrast, claim 11 requires that the first and second antibodies are each conjugated to a labeling substance, and that such labeling substances are selected such that they generate a combined signal that can be detected. See, for example, page 8, line 27 to page 9, line 16 of the specification. Furie et al. does not disclose that the labels on the first and the second antibody are selected such that they interact within one assay and generate a combined signal.

Because Furie et al. does not disclose that the labels conjugated to the antibodies are selected so as to generate a combined signal (e.g., C1 + C2), Furie et al. does not teach or suggest the subject matter of claims 11, 12, and 14. In view of the amendment and remarks herein, Applicant respectfully requests that the rejection of claims 11, 12, and 14 under 35 U.S.C. §102(b) be withdrawn.

The 35 U.S.C. §103 Rejections

Claim 13 is rejected under 35 U.S.C. §103(a) as being unpatentable over Furie et al. in view of Akhavan-Tafti et al. (U.S. Patent No. 5,843,666). The Examiner admitted that Furie et al. does not teach or suggest that the combined signal is a combined color. The Examiner asserted, however, that Akhavan-Tafti et al. disclose using alkaline phosphatase and horseradish peroxidase to produce a "detectable chemiluminescent signal (color)." This rejection is respectfully traversed.

The assay disclosed by Akhavan-Tafti et al. require using two different enzymatic reactions. The reaction disclosed by Akhavan-Tafti et al. requires the action of both a hydrolytic enzyme and a peroxidase enzyme, which are maintained in close proximity to each other, to

Applicant : Wolf Bertling
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create a chemiluminescent color. In contrast, claim 11 has been amended to recite that the "combined signal represents C1 + C2. The "combined" reaction as taught by Akhavan-Tafti et al. does not allow for a measurement of each of the two components cumulatively.

In view of the amendments and remarks herein, Applicant respectfully requests that the rejection of claim 13 under 35 U.S.C. §103(a) be withdrawn.


CONCLUSION

Enclosed is a \$60 check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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M. Angela Parsons, Ph.D.

Reg. No. 44,282

Fish & Richardson P.C., P.A.
60 South Sixth Street
Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696